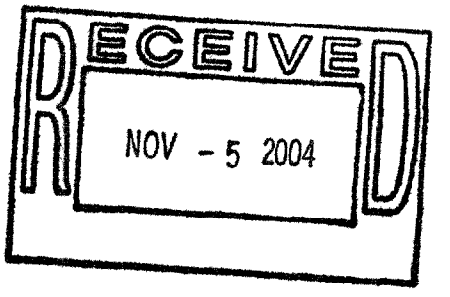
**BIONICHE**
ANIMAL HEALTH USA, INC.




November 4, 2004

Documents Management Branch (HFA–305), Room 1061
Food and Drug Administration,
5630 Fishers Lane,
Rockville, MD USA
20852

***Suitability Petition***
***Hyaluronate Sodium Injectable Solution***

Dear Sir or Madam:

Please find enclosed a suitability petition for Agency review and action. Bioniche Animal Health USA, Inc., is requesting permission to file an abbreviated new animal drug application (ANADA) for a generic hyaluronate sodium injectable solution that differs from the pioneer product (Legend®; NADA 140-883) in packaging presentation. Bioniche's product will made available not only in a 2mL and a 4mL vial, as is Legend®, but also in a 2mL pre-loaded syringe.

Your review of the enclosed petition would be greatly appreciated.

Please feel free to contact me at (613) 966-8058 should have any questions or require further information.

Sincerely,

Cindy Hickey
V.P. Corporate Quality & Regulatory Affairs
Bioniche Life Sciences Inc.

Enclosure

2004P-0507

CP1

## Suitability Petition

**Bioniche Animal Health USA, Inc.**
**Hyaluronate Sodium Injectable Solution**
**November 4, 2004**

The undersigned submits this petition under Section 512 (n)(3) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to permit the filing of an application for a generic hyaluronate sodium injectable solution that differs from the pioneer product (Legend®; NADA 140-883) in packaging presentation.

### Action Request

We are requesting that the Commissioner permit the filing of an Abbreviated New Animal Drug Application (ANADA) for hyaluronate sodium injectable solution (trade name to be determined). Our proposed product differs from the pioneer product as follows:

### Pioneer Product

**Trade Name**

Legend® (NADA 140-883)

**Active ingredients**

Hyaluronate sodium

**Strength**

10 mg/mL

**Sponsor**

Mobay Corporation

**Indications for Use**

Legend Injectable Solution is indicated in the treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis.

**Dosage Form, Routes of Administration and Recommended Dosages**

Intravenous - 4 mL vial (40 mg)

Intra-articular - 2 mL vial (20 mg) in the carpus or fetlock.

Treatment may be repeated at weekly intervals for a total of three treatments.

## Proposed Drug Product

**Trade Name**

To be determined

**Active ingredients**

Hyaluronate sodium

**Strength**

10 mg/mL

**Sponsor**

Bioniche Animal Health USA, Inc.

**Indications for Use**

Hyaluronate Sodium Injectable Solution is indicated in the treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis.

**Dosage Form, Routes of Administration and Recommended Dosages**

Intravenous - 4 mL vial (40 mg)

Intra-articular - 2 mL vial **or 2 mL syringe** (20 mg) in the carpus or fetlock.

Treatment may be repeated at weekly intervals for a total of three treatments.

## Statement of Grounds

The proposed generic product contains the same active ingredient and will be labeled with the same indications, precautions and warnings as the approved pioneer product. The route of administration and the dosage form are the same for the generic and pioneer products. The strength of the active ingredients are the same for the generic and pioneer products. The packaging presentation differs from the pioneer product in that the generic product will also be made available in a 2 mL pre-loaded syringe.

## Environmental Impact

In accordance with 21 CFR 25.33(a)(1), Bioniche Animal Health USA, Inc. requests a categorical exclusion from the requirement to file an environmental impact assessment for this action, as the generic drug will be marketed under the same conditions of approval as the previously approved animal drug.

## Economic Impact

Information pertaining to the economic impact of this petition will be submitted if requested by the commissioner.

## Certification

Bioniche Animal Health USA, Inc. certifies that this suitability petition contains all information know to them that is unfavourable to the petition.

Cindy Hickey
V.P. Corporate Quality & Regulatory Affairs
Bioniche Life Sciences Inc.

November 4, 2004
Date